Approved by Assistant to the Minister of Public Health of the USSR (T. E. Boldyrev) March 7, 1953

ACADEMY OF MEDICAL SCIENCES OF THE U.S.S.R.

Institute of Epidemiology and Microbiology
Named After Honorary Academician N. F. Gamaleya
(Moscow)

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INSTRUCTIONS

for the application of dermal anti-tularemia dry live vaccine*

1. Anti-tularemia dry live vaccine is dried matter of live culture of the vaccine family of the pathogene of tularemia.

2. With the correct application the vaccine creates an active immunity for 3 to 6 years (this is not the time limit).

3. The vaccination is done by a physician. Middle medical personnel can make inoculations under the direct guidance of a doctor only. The medical worker who is making the inoculation must be thoroughly acquainted with the directions for the application of the vaccine and must have received a practical experience with inoculations under the guidance of a doctor.

Storage and the time of suitability of the vaccine

4. The vaccine must be stored in a dark room with the temperature not exceeding 4°C (it also can be stored under a temperature well below 0°). Under these conditions the time of suitability of the vaccine is equal to two years. In case of storage of the vaccine at room temperature (18° - 20°C), the time of suitability of the vaccine is 300 days. The lower the temperature of storage, the better preserved is the activeness of the vaccine.

Note: The aforementioned suitability time is not limited. Therefore, if this series of the vaccine is not used up in the time indicated, it should not be destroyed; but it is recommended to send 4 or 5 ampules to the State Control Institute for Vaccine and Serum Named After Tarasevich (Moscow, Sivtsev Vrazhek, House No. 41) for study and for the solution of the question as to whether it is possible to prolong the time of suitability of the vaccine. The temperature at which vaccine was stored should be indicated.

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*During the vacinnation one should be guided also by the "Instruction for the prophylactic anti-tularemia inoculations," approved by the Ministry of Public Health of the USSR. In this instruction, besides the information in the aforementioned "Instruction," directions are laid down for the vaccination, the order of distribution of the vaccine, organization of inoculations, registration of the effectiveness of the vaccination and directions for revaccinations.

Counter-instructions

5. Inoculations are forbidden: if the body temperature is higher than 37°C, in the case of acute infectious diseases, decompensated heart defects, cachectic conditions of different origin, difficult chronic diseases with affection of the inner organs (kidneys, liver, etc.) in case of an active form of tuberculosis, enlargement and ailment of the lymphatic nodes, skin disease with wide affection of the cutis, bronchial asthma, if the patient is in the second half of pregnancy, if the patient is sick with tularemia according to patient anamnesis (with the presence of a positive allergical test and a certificate from the local clinic or anti-epidemic institution confirming it).

6. The anti-tularemia vaccination is forbidden with other inoculations simultaneously. Anti-tularemia vaccinations are done not earlier than the 10th day from the time of other inoculations.

After a smallpox vaccination the inoculation against tularemia is permissible not earlier than 10 days from the time that the "crust" falls off. After an anti-tularemia vaccination, other vaccinations are permissible not earlier than 10 days from the time that the crust falls off.

Diluting the vaccine

7. Directly before using, the vaccine which is contained in each ampule should be diluted in a volume of distilled water (or a specially prepared solution) which is indicated on the label. For diluting the vaccine ampules are used with the corresponding fluids which are attached to the vaccine.

8. The diluting of the vaccine is done under sterile conditions. The neck of the ampule with the vaccine or distilled water is sawed a little first, then wiped with alcohol and burned in the flame. The burning should be done carefully so as not to warm the body of the ampule in which there is the vaccine. The neck of the ampule is then broken off. The distilled water (buffer solution) which is in the special ampule is sucked into the sterilized syringe and then the volume which is indicated on the label is introduced into the ampule with the vaccine. The ampule is shaken until the dry vaccine turns into an even suspensoid. The produced microb matter is used for vaccination.

9. Before diluting and after diluting the dry vaccine, the ampule and its contents are thoroughly checked. In case there are any crevices, foreign bodies in the vaccine, unbreakable flakes and an uneven suspensoid, the ampule is rejected as defective. The ampule with the diluted vaccine is carefully protected from any possible polution during its usage.

10. Diluted vaccine which has not been used with 4 hours is destroyed by boiling or by adding to it the disinfectants (lysol 3%, carbolic acid 5%, corrosive sublimate 0.1%, chloramine 2%, alcohol 70-9) or by burning.

Mechanics of inoculation

11. Anti-tularemia dry live vaccine is used on the cutis. It is categorically forbidden to inject subdermally the vaccine for supposed cutaneous use.

12. The inoculation is done on the outside surface of the middle third of the left shoulder. The skin is cleaned with alcohol before inoculation; it is even better to rub the skin with alcohol first and then to remove the grease with ether. When the alcohol or ether evaporates, without touching the skin the vaccine is carri with the sterilized medicine dropper onto two spots of future notches, one drop each. The distance between drops is 3 - 4 cm. After that the dropper is put into the ampule with the vaccine. Further, with the left hand the skin of the arm is clutched and stretched and, with the right hand two parellel notches (not cuts!) 5 - 6 mm in length are made on it over the drops of vaccine with a smallpox inoculation feather. Care should be taken that the notches don't bleed too much; blood must come out in the size of small dew drops only. After that, the vaccine is rubbed into the notch for half a minute with the dull side of the feather. After the rubbing one should permit the vaccine to dry for 10 to 15 minutes.

Preschool children get one drop of vaccine and the notches (not more than two) should be not bigger than 2 -3 mm.

Note 1: For rubbing the skin it is forbidden to use solutions of chloramine, carbolic acid and other disinfectants because they kill the vaccine, which leads to the lowering and the loss of the effectivesness of the vaccinations.

Note 2: The vaccination feather, after each inoculation, should be boiled, rubbed with alcohol and burned in the flame, after which it should be allowed to cool off completely.

Note 3: Revaccination is done according to the same method.

Reaction to the vaccine

13. There is a local reaction of the skin almost in every case in which the inoculation took well. From the 4th or 5th day (and with some patients from the 8th or 10th day) the skin on the place of the notches swells up, reddens and itches. Along the notches there appear vesiculae the size of millet grain. Approximately from the 10th day in most cases the vesiculae change into pustules and the surrounding reddening and swelling gets larger. From the 15th day and later the pustules form a crust. From that time on all reaction symptoms diminish gradually. The small amount of infiltrate which is under the crust resolves and after the crust falls off there is a small but visible cicatrix or a light depigmatized spot on the skin.

In some cases the vesiculae, towards the 8th or 10th day, develop without changing into pustules. In some cases towards the 10th or 15th day on the skin, somewhat further from the scratch, appears a single second vesiculae.

In a number of cases towards the 8th or 15th day an enlargement of the lymphatic nodes (usually axillary ones) nearest to the vaccination place are observed.

In those cases in which the vaccination for some reason did not take well, on the skin only a traumatic reaction is registered in the form of some reddening, which remains not longer than 3 - 4 days.

14. A general reaction appears only in separate cases and is expressed in the form of indisposition, headache, more seldom in the rising of the temperature up to 38°C. The general phenomena are registered from the 3rd to 4th day after the vaccination and end after 2 or 3 days.

15. Persons who were sick with tularemia or who had the vaccination (who have the immunity!), the local reaction after the cutaneous vaccination appears after 24 - 48 hours and has basically allergic characteristics. The reddening and swelling (considerably more seldom -- small vesiculae) disappear after 3 - 5 days, more seldom remain longer.

16. Medical observation is established of the inoculated patients.

Evaluation of the taking of the vaccination and the registration of the patients

17. The taking of the vaccination is checked within 12 - 15 days after the vaccination and in the case of absence within this time of the cutis reaction on the spot of vaccination, the checking is done again on the 20th - 22nd day.

18. The persons vaccinated against tularemia are registered on the list in which family name, first name, second name, age, profession, address, date of vaccination type, series, and time of suitability of the vaccine, date of checking, the result of the vaccination during the checking on the 12th - 15th day (and with persons who did not have at that time any reaction, at checking on the 20th - 22nd day) accompanying local and general phenomena, the family name of the vaccinator are written down. A list is compiled for each village soviet (or a medical sector) according to the inhabited locality, and is saved permanently.